IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LITIGATION,	)	Master Docket: Misc. No. 21-1230
	)	MDL No. 3014
This Document Relates to: All Actions	)	

PLAINTIFFS' BRIEF IN OPPOSITION TO PHILIPS RS (F/K/A RESPIRONICS) AND THE PHILIPS DEFENDANTS' MOTION TO DISMISS FOR LACK OF STANDING PURSUANT TO FED. R. CIV. P. 12(b)(1)

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I. INTRODUCTION

Philips[1] designed, manufactured, marketed, and sold 11.3 million defective CPAP, BiPAP, and ventilator devices in the U.S. from 2008 until June 14, 2021, when they were recalled because they contained toxic polyester polyurethane ("PE-PUR") foam that is "susceptible to breaking down into particles which may then be inhaled or ingested by the user, and may emit VOCs that can also be inhaled, resulting in 'serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment.'"[2] Plaintiffs allege they suffered economic damages as a result of purchasing, leasing, renting, or reimbursing payments for Recalled Devices that Philips marketed as safe and effective breathing machines, but which were, in fact, adulterated devices that put users at risk of serious and debilitating injuries from toxic particles and fumes pumped into their airways, lungs, and throughout their bodies. Had Plaintiffs been aware of this defect, they would not have paid for the Devices.

Plaintiffs' economic damages amount to, at a minimum, the difference between the price paid for the Recalled Devices and their actual value when acquired, which was *zero* because they were worthless. This type of harm is the paradigmatic form of injury-in-fact. The Complaint sets forth how this harm is directly traceable to Philips' misconduct and avers that the payment of money damages will remedy the harm. As such, Plaintiffs have Article III standing to bring economic loss claims, and Philips' Motion[3] should be denied.

First, Philips distorts the factual basis for Plaintiffs' claims, suggesting they rely solely on

[1] "Philips" refers to Koninklijke Philips N.V., Philips North America LLC, Philips Holding USA Inc., Philips RS North America LLC, and Philips RS North America Holding Corporation.
[2] *See* Consolidated Third Amended Class Action Complaint for Economic Losses (ECF 785) ("Complaint" or "TAC"), ¶¶ 3, 5, 6, 7 (quoting Philips Recall Notices attached as Exhibit "4" to the TAC (ECF 785-4)). The devices at issue are referred to as "Recalled Devices" or "Devices." Paragraph citations ("¶" or "¶¶") refer to the TAC.
[3] "Motion" refers to the Motion to Dismiss Under Rule 12(b)(1) for Lack of Standing (ECF 911), and the Mem. of Law in Support of the Motion (ECF 912) is referred to as "Br."

the fact the "devices were voluntarily recalled." Br. at 1. Plaintiffs are suing Philips, however, because, among other things, it manufactured, marketed, and sold products purporting to be safe breathing assistance machines when it knew the Devices contained PE-PUR foam that was subject to degradation and off-gassing, putting users at risk of serious injury from inhaling or ingesting toxic particulates and VOCs. ¶¶ 4, 7. The voluntary recall of these Devices does not grant Philips immunity for its actionable misconduct.

Second, Philips mischaracterizes the nature of Plaintiffs' economic losses. Philips posits there can be no standing unless users allege the PE-PUR foam in their particular Device degraded or emitted toxic VOCs. Br. at 1. Philips' "manifestation" theory misinterprets Third Circuit law holding that injury-in-fact is adequately pled when plaintiffs allege that they received a product of lesser value than what was bargained for. In this case the presence of PE-PUR foam in each Device is what renders it worthless regardless of whether toxic particulates or gases are emitted. Plaintiffs bargained for a product that would alleviate breathing issues, that comported with Philips' representations regarding the Device's quality, that was manufactured in accordance with current good manufacturing practice requirements ("GMPs"), that was unadulterated, and that satisfied regulatory requirements. Instead, Plaintiffs received Devices that the FDA found "present an unreasonable risk of substantial harm to the public health." ¶¶ 248-54, 315. Plaintiffs allege that had they known of the true nature of the Devices, they would not have paid for them, ¶ 20, a logical conclusion since the Devices were marketed as safe breathing assistance devices, but the defect undermined that purpose. The inclusion of PE-PUR foam rendered the Devices adulterated and worthless "because they can neither be demanded nor supplied: they cannot be legally sold, received, or delivered in interstate commerce." ¶ 254.

Philips' additional arguments—that its remediation and replacement program negates

standing and that commercial plaintiffs, *e.g.*, hospitals and third-party payors ("TPPs"), cannot have standing—are equally flawed and inconsistent with well-settled law, as set forth below.

II. ARGUMENT

A. Legal Standard Governing Article III Standing Analysis

To establish standing, Article III requires a plaintiff to demonstrate: an (1) injury-in-fact; (2) that is fairly traceable to the challenged conduct; and (3) is likely to be redressed by a favorable decision. *Clemens v. ExecuPharm Inc.*, 48 F.4th 146, 152 (3d Cir. 2022). As explained by the Third Circuit Court of Appeals, "[i]njury-in-fact is not Mount Everest." *Danvers Motor Co. v. Ford Motor Co.*, 432 F.3d 286, 294 (3d Cir. 2005) (Alito, J.). "The contours of the injury-in-fact requirement, while not precisely defined, are very generous, requiring only that claimant allege[] some specific, identifiable trifle of injury." *In re Horizon Healthcare Servs. Inc. Data Breach Litig.*, 846 F.3d 625, 633 (3d Cir. 2017) (citation omitted).

Where, as here, a defendant asserts a facial attack on a plaintiff's Article III standing under 12(b)(1), *see* Br. at 4, the Court should apply the same standard it would apply to a motion to dismiss under Rule 12(b)(6), looking only to the allegations of the complaint and interpreting them in the light most favorable to the plaintiff. *See Ballentine v. United States*, 486 F.3d 806, 810 (3d Cir. 2007); *Cole's Wexford Hotel, Inc. v. UPMC*, 127 F. Supp. 3d 387, 399-402 (W.D. Pa. 2015). Moreover, the court must "separate [its] standing inquiry from any assessment of the merits of the plaintiff's claim" and assume "that a plaintiff has stated valid legal claims." *Cottrell v. Alcon Labs.*, 874 F.3d 154, 162 (3d Cir. 2017).

B. Plaintiffs Allege Economic Loss, a Paradigmatic Form of Injury-in-Fact

Philips' primary challenge to standing is that Plaintiffs have not alleged injury-in-fact. However, "[f]inancial harm is a 'classic' and 'paradigmatic form' of injury in fact." *Adam v. Barone*, 41 F.4th 230, 234 (3d Cir. 2022) (alterations in original omitted). And a plaintiff

adequately alleges injury-in-fact where "the purchase provided her with an economic benefit worth less than the economic benefit for which she bargained." *In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Pracs. & Liab. Litig*. ("*J&J Talc*"), 903 F.3d 278, 290 (3d Cir. 2018).

That is precisely what Plaintiffs allege here—the quintessential pocketbook injuries recognized as sufficient in *Adam* and *J&J Talc*—*i.e*., they paid for breathing assistance Devices that purportedly were manufactured in accordance with GMPs, were unadulterated, and were regulatory compliant.[4] ¶¶ 245-47. Instead, the Devices did not meet these standards, ¶¶ 248-54, and "present an unreasonable risk of substantial harm to the public health," ¶ 315.

Specifically, each Device contained PE-PUR foam, which is prone to degradation and emission of harmful particulates and toxic VOCs that are pumped into a patient's airways, lungs, and throughout their body. ¶¶ 255-88. Because of this, the Devices did not help users breathe, did not comport with Philips' quality representations, did not comply with GMPs, are considered "adulterated," and are not regulatory compliant. ¶¶ 248-54. By law, they cannot be sold, should not have been sold, and are, therefore, worthless. *Id.*[5]

Plaintiffs' allegations of economic injury are neither novel nor implausible. Within this Circuit, several courts have considered similar allegations of injury and held that they were sufficient to allege Article III standing for both consumer and commercial plaintiffs. For example, "deviations from and violations of" GMPs, and plaintiffs' resulting exposure to potential

[4] Philips marketed the Devices as a "quality system[]" that would help users to "[b]reathe easier, sleep more naturally" and that were "clinically proven" to treat sleep disorders. ¶ 358.

[5] Philips argues that Plaintiffs' injuries rely on FDA regulations, claiming that such reliance supports its preemption claim. Br. at 8 n.10. Plaintiffs' injuries do not arise solely from regulatory violations but rather from misconduct that violates both federal and state law duties. *See, e.g., In re Metformin Mktg. & Sales Prac. Litig.*, 2022 WL 970281, at *7 (D.N.J. Mar. 30, 2022). *See also* Plaintiffs' Br. in Opp. to Philips RS's Motion to Dismiss Pursuant to Rule 12(b)(6), Sections IV.A.1 & 2, filed February 6, 2023, and incorporated herein by reference.

carcinogens, have been found to be a valid basis for alleging economic injury. *In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig*., 2021 WL 100204, at *1-2, *4 (D.N.J. Jan. 12, 2021). The plaintiffs in *Valsartan*—consumers and TPPs—alleged that the drugs they purchased "were 'worthless' because [plaintiffs] bargained for a pure, unadulterated, properly branded, and []GMP compliant generic drug but received an impure, adulterated, misbranded, non []GMP compliant, and illegal generic drug." *Id.* at *9. These allegations were "sufficient for a factfinder to determine the Plaintiffs suffered at least some economic injury." *Id*.

Similarly, where an insurance company paid for drugs "believing they were manufactured in compliance with []GMPs but received drugs that were non-compliant and therefore worth less than what they paid," the court rejected defendants' standing arguments and denied summary judgment. *Blue Cross Blue Shield Ass'n v. GlaxoSmithKline LLC*, 417 F. Supp. 3d 531, 554 (E.D. Pa. 2019) (citing defendant's expert's admission that lack of assurance of drugs' quality would render them "worthless"); *see also Metformin*, 2022 WL 970281, at *1, *4, *6 (finding injury-in-fact when drugs were contaminated because the non-GMP compliant drugs were "worthless").[6]

C. Philips' "Manifestation" Argument Is Misguided

Philips makes several arguments stemming from the idea that Plaintiffs cannot establish Article III standing without alleging that their specific Devices have "manifested a defect" by emitting PE-PUR particulates or toxic VOC gases. Br. at 4-7.[7] Philips claims that without

[6] *Cf. Hubert v. Gen. Nutrition Corp*., 2017 WL 3971912, at *4, *7-9 (W.D. Pa. Sept. 8, 2017) (Hornak, C.J.) (complaint alleging misrepresentations regarding dietary supplements dismissed for lack of standing on grounds that an injury-in-fact did not occur because the product performed as intended; however, the decision predated the Third Circuit's ruling in *J&J Talc*, and in *Hubert*, unlike here, the plaintiff did not allege that the products were worthless because they could not be lawfully sold nor did he allege that the products "failed to work for their intended purpose or did not deliver the advertised benefits."); *see also Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1087 (11th Cir. 2019) (distinguishing *Hubert*).

[7] Philips ignores that "harm due to foam degradation 'may not be immediately recognizable and may not be something that the customer would/could report,'" ¶ 267; Plaintiffs were warned not

"manifestation," the injury must arise from the recall, and the Devices cannot plausibly be "worthless." *Id.*[8] These arguments mischaracterize Plaintiffs' allegations and misstate the law.

Plaintiffs allege they suffered economic injury because they did not get the benefit of their bargain. Their injuries arise from Philips' misconduct related to the manufacturing, marketing, and selling of products that Philips knew did not perform the functions that consumers thought the Devices performed and instead, threatened to cause grave physical harm to users.[9] That is wholly distinct from whether Philips recalled the Devices.

With respect to the value of the Devices, Plaintiffs allege the presence of PE-PUR foam rendered *every* Device non-compliant with FDA standards, adulterated, and unsaleable. Because the Devices have PE-PUR foam and should never have been sold, they are worthless. Plaintiffs' economic injuries do not depend on whether the foam in the Devices has emitted toxic particulates or gas; the Devices are worthless regardless, because they have no economic value. Moreover, contrary to Philips' self-serving statements, the Devices *did not perform as intended*: instead of providing a "clinically proven" "quality system[]" that would help users to "[b]reathe easier, sleep

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remove foam from their devices, ¶ 420; and opening the devices could cause escape or destruction of relevant particulate evidence. *See Schmid v. Milwaukee Elec. Tool Corp.*, 13 F.3d 76, 81 (3d Cir. 1994) (discussing evidence spoliation). *See also* Amended Preservation Orders (ECF 773 & ECF 968).

[8] Philips also argues the Devices cannot be "worthless" because Philips will eventually replace the foam. Br. at 7-8. *See* Plaintiffs' response in Section II.E, *infra*. Further, Philips mischaracterizes Plaintiffs' claims as impermissibly seeking damages for statutory violations without further alleging a "concrete harm." Br. at 8 (citing *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2206 (2021)). Unlike the plaintiffs in *TransUnion*, Plaintiffs here are not seeking statutory damages arising from an "intangible harm," but instead are asserting concrete "monetary harm." *Id*. at 2197.

[9] Philips relies upon two opinions in the *McNeil* litigation, but those opinions were issued prior to the Third Circuit's guidance in *J&J Talc* and *Cottrell*. Moreover, the *McNeil* opinions are distinguishable on their facts. *See In re McNeil Consumer Healthcare, Mktg. & Sales Pracs. Litig*., 2011 WL 2802854, at *14 (E.D. Pa. July 15, 2011) ("*McNeil I*") (Plaintiffs did not identify the precise manner in which they were harmed) and *In re McNeil Consumer Healthcare, Mktg. & Sales Pracs. Litig*., 877 F. Supp. 2d 254, 259 n.6, 271 (E.D. Pa. 2012) ("*McNeil II*") (some drugs not recalled, and some were not purchased from the same facility where GMP violations found).

more naturally," ¶ 358, the Devices posed such a significant health risk, ¶¶ 256, 259-88, 420, that the FDA found "a reasonable probability that the use or exposure to [the Devices] will cause serious health consequences or death," ¶¶ 382, 620-21, which is why Philips advised users to stop using recalled CPAP and BiPAP machines and consider ceasing use of recalled ventilators, ¶¶ 380-81, 383-84.

Third Circuit law recognizes that plaintiffs can plead Article III economic injury by alleging *either* that a product "failed to work for its intended purpose" *or* that it "was worth objectively less than what one could reasonably expect." *Koronthaly v. L'Oreal USA, Inc.*, 374 F. App'x 257, 259 (3d Cir. 2010); *see also Am. Fed'n of State, Cnty. & Mun. Emps. v. Ortho-McNeil-Janssen Pharms., Inc.*, 2010 WL 891150, at *3 (E.D. Pa. Mar. 11, 2010) (finding that purchase of recalled products conferred standing regardless of whether specific items contained the defect; plaintiffs alleged "an economic loss that is concrete [and] particular"); *Blue Cross Blue Shield Ass'n v. GlaxoSmithKline LLC*, 2016 WL 6612804, at *6 (E.D. Pa. Nov. 9, 2016) ("Regardless of whether the at-issue drugs were fit for consumption, 21 U.S.C. § 331(a) prohibits the introduction of adulterated drugs into interstate commerce, and Plaintiffs allege the at-issue drugs were rendered worthless because they were sold illegally.").[10]

Philips' reliance on *J&J Talc* is misplaced. *See* Br. at 5-6. *J&J Talc* holds that if a plaintiff's theory of standing is premised on an economic injury that arises from the purchase of a product, then the plaintiff must allege that the purchase provided her with an economic benefit less than

[10] Philips relies on authorities from the Eighth Circuit, which, unlike the Third Circuit, explicitly rejects the benefit-of-the-bargain approach. *See, e.g., Johannessohn v. Polaris Indus. Inc.*, 9 F.4th 981, 988 (8th Cir. 2021); *Wallace v. ConAgra Foods, Inc.*, 747 F.3d 1025, 1030-31 (8th Cir. 2014); *Briehl v. Gen. Motors Corp.*, 172 F.3d 623, 628 (8th Cir. 1999); *O'Neil v. Simplicity, Inc.*, 553 F. Supp. 2d 1110, 1116 (D. Minn. 2008), *aff'd*, 574 F.3d 501 (8th Cir. 2009); *In re Polaris Mktg., Sales Pracs., and Prod. Liab. Litig.*, 364 F. Supp. 3d 976, 984 (D. Minn. 2019).

that for which she bargained. 903 F.3d at 290. *J&J Talc* does not require plaintiffs to allege that the product at issue has failed or that the risks associated with the defect have already occurred. Indeed, the opinion recognizes the short-sightedness of such an approach. *Id.* at 281 n.4, 281-82, 289 (suggesting a plaintiff could establish Article III standing if the product at issue was an "automobile [] at risk of imminently malfunctioning because of a particular defect," and plaintiff could have established standing if she alleged the risk of future harm). Ultimately, the Third Circuit Court of Appeals has found purchasers to have standing, even if their products otherwise perform as expected, when they are able to demonstrate that they received an economic benefit less than what was bargained for. *See Cottrell*, 874 F.3d at 161-69.[11]

Courts beyond this Circuit have reached a similar conclusion. *See Debernardis,* 942 F.3d at 1080, 1083, 1086 (concluding "the plaintiffs plausibly alleged that they suffered an economic loss when they purchased supplements that were worthless because the FDCA prohibited sale of the supplements"; allegations "that the supplements failed to perform as advertised" or "caused any adverse health effects" may be "*sufficient*" but are not "*necessary*") (emphasis in original); *In re Aqua Dots Prod. Liab. Litig.*, 654 F.3d 748, 750 (7th Cir. 2011) (holding that economic injury was established, even though risk did not materialize, because plaintiffs would not have purchased the product had they known of its risks); *Franz v. Beiersdorf, Inc.*, 745 F. App'x 47, 49 (9th Cir.

[11] Philips relies upon a number of authorities that are inapposite because they hinge on very different facts and typically poorly pled economic theories. *See Rivera v. Wyeth-Ayerst Labs*, 283 F.3d 315, 317 (5th Cir. 2002) (drug at issue did not violate FDA regulations); *Earl v. Boeing Co.*, 53 F.4th 897, 903 (5th Cir. 2022) (economic injury theory based on flawed assumptions regarding supply and demand); *Hadley v. Chrysler Grp., LLC*, 624 F. App'x 374, 377-78 (6th Cir. 2015) (alleged damages could not be traced to defective warning light); *Myers-Armstrong v. Actavis Totowa*, LLC, 2009 WL 1082026, at *4 (N.D. Cal. Apr. 22, 2009) (plaintiff did not allege "a rational fear of future harm" from consuming her product, which was not recalled), *aff'd*, 382 F. App'x 545 (9th Cir. 2010); *Williams v. Purdue Pharma Co.*, 297 F. Supp. 2d 171, 175 (D.D.C. 2003) (theory of economic injury from drug purchase was not based on violation of FDA regulations).

2018) (injury-in-fact where product should not have been sold).[12]

D. The Commercial Plaintiffs Properly Allege Article III Standing

Injury-in-Fact. Philips erroneously argues that the commercial Plaintiffs cannot establish injury-in-fact because they have not alleged how they are "worse off financially," since they would have had to pay for some device to treat patients' sleep apnea if they did not pay for a defective Philips product. Br. at 9-10 & n.11. This abbreviated version of the standing analysis sidesteps the reality that hospitals and TPPs are no different from consumers in that they paid (in whole or part) for an FDA-compliant device, but they received a non-compliant, adulterated, nonsaleable (and therefore worthless) Device.[13] Their status as a commercial entity does not negate their standing to bring claims for payment for a Device where they did not receive the benefit of their bargain. *See Kinetic Co. v. Medtronic, Inc*., 672 F. Supp. 2d 933, 942 (D. Minn. 2009); *ASEA/AFSCME Loc. 52 Health Benefits Tr. v. St. Jude Med., LLC*, 362 F. Supp. 3d 642, 647 (D. Minn. 2019); *Metformin*, 2022 WL 970281, at *4; *Valsartan*, 2021 WL 100204, at *9; *Blue Cross*, 417 F. Supp. 3d at 554; *Am. Fed'n of State Cty. & Mun. Employees*, 2010 WL 891150, at *4.

Philips further argues, without any authority, that the hospital plaintiffs must allege expenses and lost profits caused by the Defect—injuries that are *in addition to* the price of the Device—for an economic injury to be plausible. Br. at 9. This is incorrect. Even if a hospital

[12] *See also Crawford v. FCA US LLC*, 2021 WL 3603342, at *2 (E.D. Mich. Aug. 13, 2021) (finding that plaintiffs whose vehicles never malfunctioned had standing because they were injured at the point of sale by paying more than they would have paid had they known of the defect); *Yachera v. Westminster Pharms*., LLC, 477 F. Supp. 3d 1251, 1264 (M.D. Fla. 2020) (plaintiff pleads injury-in-fact when she "pleads that she would not have purchased the medication had she known it was defective.").

[13] Philips' argument would bar all purchasers—TPPs and consumers—from seeking redress for losses resulting from the purchase of any defective medical device or drug. Under the Philips paradigm, consumers needing a drug or device for medical reasons would not have standing to recover the purchase price of a defective product because they would have had to pay for another drug or device anyway. That result is not the law and is contrary to public policy.

"obtained revenue" from treating patients with a Device (a fact not in the record), a hospital, like all other Plaintiffs, is out-of-pocket for having paid for a Device that is worthless.

The injury is "fairly traceable." Philips argues the traceability element of Article III standing cannot be met because the prescribing decisions of physicians make the causal connection between Plaintiffs' injury and Philips' conduct too speculative.[14] Br. at 10-11. But that very argument was rejected by the Third Circuit Court of Appeals when assessing a TPP's standing under RICO's "proximate cause" standard. *In re Avandia Mktg., Sales Pracs. & Prod. Liab. Litig.*, 804 F.3d 633, 645 (3d Cir. 2015) (concluding the drug manufacturer's misrepresentations, not a doctor's decision to prescribe a drug or a patient's decision to take the drug, caused the TPPs' injuries). Accordingly, because Article III standing applies the more lenient "fairly traceable" standard, it follows that the prescribing decisions of physicians do not break the chain of causation. *See Metformin*, 2022 WL 970281, at *4 (complaint adequately pled that "the defendant's challenged actions, and not the actions of some third party, caused the plaintiff's injury"); *Blue Cross,* 417 F. Supp. 3d at 556 (testimony that TPP would have restricted coverage for drugs had it known of GMP violations held sufficient to defeat motion for summary judgment on causation).[15]

[14] The out-of-circuit decisions Philips relies on are inapposite and, in any event, contrary to controlling authority. *Laborers Loc. 17 Health & Benefit Fund v. Philip Morris, Inc.*, 191 F.3d 229, 243 (2d Cir. 1999), held that the TPP's injury was too attenuated because it was derivative of physical injuries suffered by plaintiffs, which is not the case here. *United Food & Com. Workers Cent. PA & Reg'l Health & Welfare Fund v. Amgen, Inc.*, 400 F. App'x 255, 257 (9th Cir. 2010), held that the chain of causation was too attenuated because it "involved at least four independent links," links that are not involved in this case. Regarding *In re Guidant Corp. Implantable Defibrillators Prod. Liab. Litig.*, 484 F. Supp. 2d 973 (D. Minn. 2007), subsequent opinions from the same district disagreed with and declined to follow its holding. *See Kinetic Co.*, 672 F. Supp. 2d at 942; *accord ASEA/AFSCME Loc. 52 Health Benefits Tr.*, 362 F. Supp. 3d at 647.

[15] Other Circuits have reached the same conclusion. *See, e.g., Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharms. Co. Ltd.*, 943 F.3d 1243, 1257 (9th Cir. 2019) (explaining that if prescribing physicians' decisions "sever[ed] the chain of proximate cause," drug manufacturers would be insulated from liability for fraudulent marketing schemes); *In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 21, 38-39 (1st Cir. 2013) (concluding that a causal

Injury was not derivative or duplicative. Philips is wrong in claiming that the injury alleged by TPPs is derivative or duplicative. Br. at 11-12. As explained by the Third Circuit Court of Appeals, derivative injury is one in which the plaintiff seeks to recover for a "harm that was derivative of harm suffered by a more immediate victim." *Avandia*, 804 F.3d at 644. Because each Device here was paid either in whole or part directly by the TPP, with the balance to be paid by the insured consumer, the TPP's harm is direct and not derivative of a harm to another party. *See id.* ("The injury alleged by the TPPs is an economic injury independent of any physical injury suffered by Avandia users."); *In re Wellbutrin XL Antitrust Litig*., 260 F.R.D. 143, 156 (E.D. Pa. 2009) ("The injury is alleged to have impacted the [TPP] plaintiffs themselves through the act of reimbursing their members."); *In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 531 (3d Cir. 2004) (recognizing TPPs "have litigable claims against [a drug manufacturer] as injured purchasers").

Because the TPPs' injury is direct, "[t]here is no risk of duplicative recovery." *Avandia*, 804 F.3d at 646; *see also In re Lipitor Antitrust Litig*., 2020 WL 5642175, at *3 (D.N.J. Sept. 22, 2020) ("Consumers and third-party payors are injured by different portions of the same ... purchase and related overcharge. The consumers' portion ... is their copayment and the third-party payor's portion ... is the remainder."); *Desiano v. Warner-Lambert Co*., 326 F.3d 339, 350 (2d Cir. 2003) ("[E]ach [health benefit provider] and its patient co-payer has its own, segregable, claim for economic harm, to the extent of their respective co-pay."); *Painters*, 943 F.3d at 1251 ("[T]here is no concern of 'duplicative recoveries by plaintiffs removed at different levels of injury from the violation.'") (internal citation omitted).[16]

chain from manufacturer to TPP is expected and "anything but attenuated").

[16] The cases Philips relies upon fundamentally differ. *Serv. Employees Int'l Union Health & Welfare Fund v. Philip Morris Inc*., 249 F.3d 1068, 1069 (D.C. Cir. 2001), did not address Article

Simply put, Philips is liable for the full amount of economic loss caused by its conduct, not just that portion of economic loss attributable to the portion paid by the consumer using the Device.

E. The Repair and Replacement Program Does Not Defeat Article III Standing

Philips contends "the existence" of its repair and replacement program deprives plaintiffs of Article III standing. Br. at 5, 12. However, this ignores the allegation that the injury occurred at the time of purchase. Moreover, the fact that a defendant takes action that it characterizes as a "remedy" does not defeat standing. *See Adam*, 41 F.4th at 234-36 (clarifying that a defendant's refund offer does not "categorically deprive a plaintiff of her day in court"); *Potts v. Johnson & Johnson Consumer Inc*., 2021 WL 2177386, at *7 (D.N.J. May 28, 2021) (rejecting defendant's argument that plaintiff's acceptance of partial refund defeated standing); *McNeil II*, 877 F. Supp. 2d at 273 ("[T]he mere existence of a refund offer is not sufficient to defeat standing"). Whether a recall adequately addresses the complained-of problem is a question of fact that typically cannot be resolved on the pleadings. *See Reynolds v. FCA US LLC*, 546 F. Supp. 3d 635, 647-48 (E.D. Mich. 2021) (rejecting argument that plaintiffs had to show recall would be ineffective to maintain subject matter jurisdiction and noting that effectiveness of repair is "deeply entwined" with merits of claims).

In addition, where the plaintiff seeks meaningful relief beyond the measures the defendant has offered or taken, courts have held that the defendant's recall measures do not defeat plaintiff's standing. *Payne v. Progressive Fin. Servs., Inc.*, 748 F.3d 605, 607-08 (5th Cir. 2014) ("When a defendant does not offer the full relief requested, the plaintiff maintains a personal stake in the outcome of the action, the court is capable of granting effectual relief outside the terms of the offer,

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III standing. Multiple courts recognize the difference between cases like this and the tobacco cases cited by Philips where plaintiffs "suffered a loss because of the harm that the defendants brought upon" a third party. *Avandia*, 804 F.3d at 645; *Desiano*, 326 F.3d at 349 (explaining differences).

and a live controversy remains."); *Coffelt v. Kroger Co*., 2017 WL 10543343, at *5-6 (C.D. Cal. Jan. 27, 2017) (finding that recall and refund program did not defeat standing because plaintiff sought additional relief that could be redressed by favorable decision from court); *Lengen v. Gen. Mills, Inc*., 185 F. Supp. 3d 1213, 1221 (E.D. Cal. 2016) (holding that recall and refund offer did not moot damages claims); *Verde v. Stoneridge, Inc.*, 137 F. Supp. 3d 963, 971-72 (E.D. Tex. 2015) (rejecting argument that refund, repair or replacement offers deprived plaintiff of standing).

Here, Plaintiffs have alleged that the repair and replacement program is inadequate and ineffective, ¶¶ 19, 414-23, especially in light of: the fact that certain of Plaintiffs' Devices are not part of the program (*id.*); the FDA's admonitions concerning the delays and inadequacy of the program, ¶¶ 409-13, 423; the dangers posed by the Devices, ¶¶ 255-88, 380-84, 420; the program's failure to offer a refund, ¶¶ 414-23; the fact that many Plaintiffs still have not received a refurbished device, *id.*; and the time and money needed to comply with Philips' directives to stop using CPAP and BiPAP devices, confer with physicians and equipment suppliers, find safe alternatives,[17] and determine if the benefit of use outweighs the risks, ¶¶ 381-84.

Further, Plaintiffs assert RICO and state law claims arising from Philips' false representations about the safety and efficacy of the Devices, ¶ 21, but the repair program does not offer remedies available under those laws, such as punitive or treble damages, statutory damages, and attorneys' fees. Because complete relief is not afforded, Plaintiffs' standing is not affected. In fact, plaintiffs who allege economic losses maintain standing *even if* a recall effectively addresses

[17] Numerous Plaintiffs paid for replacement devices. ¶¶ 22-150. Philips' argument that such a purchase "cannot give rise to an economic injury" unless plaintiffs plead that "an immediate replacement was necessary," Br. at 13, is belied by: Philips' instruction to discontinue use of the devices and find alternatives, ¶¶ 381-84; the fact there was no repair and replacement program when the recall was announced, ¶¶ 405, 414-15; the recognition that the harm "may not be immediately recognizable and may not be something that the customer would/could report," ¶ 267; and the warning that users should not remove foam from their devices, ¶ 420.

the defect. *Crawford*, 2021 WL 3603342, at *3; *Raymo v. FCA US LLC*, 475 F. Supp. 3d 680, 695 (E.D. Mich. 2020).

None of the decisions cited by Philips compels a different conclusion. The Complaint contains the types of allegations found to be lacking in *McNeil I*, 2011 WL 2802854, at *9-10, *12-13, including which products Plaintiffs purchased, ¶¶ 22-150; how the products were defective, ¶¶ 248-88; and why the "relief" offered in the recall is inadequate, ¶¶ 387-427. Moreover, the dismissal for lack of standing in *Hadley* v. *Chrysler Grp., LLC*, 2014 WL 988962, at *5 (E.D. Mich. Mar. 13, 2014), *aff'd*, 624 F. App'x 374 (6th Cir. 2015), did not rest on the fact that defendant "promised to repair product free of charge," *cf.* Br. at 13, but rather on plaintiffs' failure to allege actual injury that was causally related to their claim for delay in implementing a recall. 624 F. App'x at 376-80[18]; *Crawford*, 2021 WL 3603342, at *2-3 (distinguishing *Hadley*); *Reynolds*, 546 F. Supp. 3d at 647-48 (same); *Raymo*, 475 F. Supp. 3d at 693-95 (same).

F. Philips' Arguments Regarding Absent Class Members and Models Not Purchased by Named Plaintiffs Are Premature

Relying on out-of-circuit district court cases that are counter to the weight of authority, Philips contends Plaintiffs lack standing to assert claims on behalf of absent class members under the laws of states in which they do not reside. But courts within the Third Circuit generally reject this argument. *See In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.*,

[18] Other cases cited by Philips are inapposite. Br. at 5, 12. In *Johnson v. Guhl*, 357 F.3d 403, 412 (3d Cir. 2004), the claim at issue was not tied to any injury plaintiffs could have suffered. The portion of *Burbank v. BMW of N. Am., LLC*, 2022 WL 833608 (D.N.J. Mar. 21, 2022) that Philips cites did not address standing but whether the "mere existence of a recall" was sufficient to prove the vehicle in question had a "nonconformity." *Id.* at *9. Elsewhere the court concluded that plaintiff maintained standing after defendants repaired his vehicle and paid him $1,000 because the recall did not provide all the relief plaintiff sought. *Id.* at *4. Similarly, neither *Heard v. FCA US, LLC*, 2020 WL 1285743, at *1, *3 (N.D. Ala. Mar. 16, 2020) nor *Hughes v. Stryker Sales Corp.*, 2010 WL 1961051, at *4 (S.D. Ala. May 13, 2010), *aff'd sub nom. Hughes v. Stryker Corp.*, 423 F. App'x 878 (11th Cir. 2011) involved standing but rather whether plaintiffs could defeat motions for summary judgment, without expert testimony.

2022 WL 1013945, at *5 (D.N.J. Apr. 5, 2022); *In re Generic Pharms. Pricing Antitrust Litig.*, 368 F. Supp. 3d 814, 831 (E.D. Pa. 2019); *In re Liquid Aluminum Sulfate Antitrust Litig.*, 2017 WL 3131977, at *19 (D.N.J. July 20, 2017); *see also In re Asacol Antitrust Litig.*, 907 F.3d 42, 50 (1st Cir. 2018); *Langan v. Johnson & Johnson Consumer Companies, Inc.*, 897 F.3d 88, 95 (2d Cir. 2018).

Whether the claims of absent class members in states in which no named Plaintiff resides can be adjudicated relates to class certification, not standing, and so should not be decided at this juncture. *In re Chocolate Confectionary Antitrust Litig.*, 602 F. Supp. 2d 538, 579 (M.D. Pa. 2009) (deferring issue until class proceeding); *accord In re Thalomid & Revlimid Antitrust Litig.*, 2015 WL 9589217, at *19 (D.N.J. Oct. 29, 2015).

Similarly, whether Plaintiffs lack standing to assert claims on behalf of absent class members who purchased devices that no named Plaintiffs purchased is an issue of class certification, not standing. *Diebler v. SanMedica Int'l, LLC*, 2022 WL 16552777, at *5 (D.N.J. Oct. 31, 2022); *In re L'Oreal Wrinkle Cream Mktg. & Sales Pracs. Litig.*, 2013 WL 6450701, at *4 (D.N.J. Dec. 9, 2013). When courts address this issue as part of the standing inquiry, the better-reasoned decisions conclude that plaintiffs have standing, especially where, as here, there are "substantial similarities" among the products (*i.e.*, they all contain PE-PUR foam) and among the alleged misrepresentations about the products. *See, e.g.*, *Quinn v. Walgreen Co.*, 958 F. Supp. 2d 533, 542 (S.D.N.Y. 2013); *Brown v. Hain Celestial Grp., Inc.*, 913 F. Supp. 2d 881, 892 (N.D. Cal. 2012). Philips' suggestion that there is an absolute bar on plaintiffs representing absent class members who purchased different products is contrary to the weight of authority.

III. CONCLUSION

The Motion should be denied. If the Court should grant any portion of the Motion, Plaintiffs respectfully request leave to file an amended complaint.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was filed via the Court's CM/ECF system on this 6th day of February 2023 and is available for download by all counsel of record.

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